Election / #4
5/23/02

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Carol O. Cowing	Group Art Unit 1642
Appl. No.	:	09/809,158	
Filed	:	March 15, 2001	
For	:	METHOD TO ENHANCE THE IMMUNOGENICITY OF AN ANTIGEN	
Examiner	:	Ungar, S.	

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first-class mail in an envelope addressed to: United States Patent and Trademark Office, P.O. Box 2327, Arlington, VA 22202, on

May 8, 2002
(Date)

Mark R. Benedict, Reg. No. 44,531

RESPONSE TO RESTRICTION REQUIREMENT

United States Patent and Trademark Office
P.O. Box 2327
Arlington, VA 22202

Dear Sir:

Applicant wishes to thank the Examiner for speaking with Applicant's representative, Mark R. Benedict, on April 25, 2002 regarding clarification of the Restriction Requirement mailed on April 9, 2002.

Independent Inventions Restriction

In response to the Restriction Requirement, Applicant elects with traverse, Group I (claims 1-14, 18-24, 27-47 and 51-57).

Applicant traverses the restriction and respectfully asserts that an "implied Markush group" is an improper basis for a restriction requirement. Independent claim 1 recites "[a] method for vaccinating a mammal against an antigen, comprising: (1) introducing into the mammal an effective dose of the antigen or an epitope(s) thereof; and (2) administering to the mammal a topical treatment in an amount sufficient to increase the number of antigen-bearing dendritic cells in a lymphoid organ...". The embodiments identified by the Examiner as purported elements of the "implied Markush group" (i.e., Groups I-III; a lipophilic molecule (claim 2), a lipophilic molecule and an organic solvent (claims 15-16), and ultrasound energy (claim 17)) each correspond to a different topical treatment (recited in the second step of claim

1)). It is respectfully pointed out that while these topical treatments are different from one another, they share the same objective and criteria for success (i.e., increasing the number of antigen-bearing dendritic cells) and are linked by claim 1. Thus, Applicant asserts that these topical treatments are not independent inventions, unconnected in design, operation, or effect, but rather species of the genus "topical treatment" recited in the administering step (2) of generic claim 1.

The fourth alleged element of the "implied Markush group" (i.e., Group IV; transformation of a cell within the mammal (claims 25-26)) corresponds to a particular method of introducing the antigen into the mammal (recited in the first step of claim 1). Thus, claims 25-26 recite one species of the introducing step (1) encompassed by generic claim 1. The other species of introducing an antigen into the mammal are recited in claims 18-24, and linked to claims 25-26 by generic claim 1. The Examiner subsequently indicated that these other species were subject to election of a single species of methods of introducing the antigen, thus, supporting Applicant's contention that the various methods of introducing an antigen into a mammal are merely species of the genus recited in claim 1.

Applicant has a statutory right under 35 U.S.C. §112, ¶2-4, to claim the subject matter which she regards as her invention and to define varying scopes of her invention through the use of independent and dependent claims. In the present application, for example, claim 1 is an independent (genus) claim that links two or more dependent (species) claims. Under such circumstances, restriction among the linked inventions is properly conditioned on non-allowance of the linking claim. *See* MPEP §809.03, Form Paragraph 8.12. Thus, whereas a species restriction conditioned on non-allowance of the linking claim may be asserted, restriction as independent inventions is not appropriate.

The undersigned is unaware of any authority for the proposition that a generic claim reciting no Markush group should nevertheless be considered as a Markush claim, simply because dependent claims recite various species. A large proportion of the independent claims in all the pending patent applications in the office satisfy that definition. Almost invariably, they are examined without restriction - although in a minority of cases, an election requirement will issue depending on the number of species recited in dependent claims. Otherwise, the Applicant would be deprived of her statutory right to claim the full patentable scope of her invention - as

defined by the current independent claim. Under the PTO's restriction requirement, she would get only four pieces of that claim in four separate patents - with no coverage at all for the rest of the subject matter (i.e., subject matter encompassed by the generic claim but not the particular species).

In view of the foregoing remarks, Applicant respectfully requests the Examiner to withdraw the Requirement for Restriction to one of Groups I-IV.

The Examiner also indicated that Group I was further subject to election of a single species comprising different lipophilic molecules, which are represented by the generic formulas (1), (2) and (3) recited in Claims 3 and 36. Applicant elects the species set forth in structure (2). Applicant respectfully traverses the species election, because only three closely related generic structures are disclosed. They are linked by generic claims 2 and 35, respectively.

The Examiner also indicated that Groups I-III were further subject to election of a single species of methods of introducing the antigen, which species are set forth in claims 18-24 and 54-56. Applicant elects the species set forth in claim 21. Applicant respectfully traverses the species election with respect to claims 18-24, because only six species of well-known methods of introducing are disclosed and they are all encompassed by the introducing step of generic claim 1.

The Examiner also indicated that Groups I-IV were further subject to election of a single species of antigen, which "species" are both set forth in claim 27 as (a) normal and (b) pathologic antigens. Applicant elects the "pathologic" species of antigen.

The Examiner also indicated that Groups I-V were further subject to election of a single species wherein the topical treatment has different effects on function, which different effects are set forth in claims 28-31. Applicant elects the species set forth in claim 28. Applicant respectfully traverses the species election with respect to claims 28-31, because only three species of different effects on function are disclosed and the specification teaches (see, pg. 28-29, paragraphs (1)-(6)) that each of these effects may occur and be monitored as related criteria of success (i.e., the objective of the invention). In other words, the effects are not mutually exclusive.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 5/8/02

By: _____

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